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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,747	12/19/2001	Stuart Edwards	9222.16399-D DIV	4434

7590

10/24/2005

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,747	Applicant(s) EDWARDS ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/12/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received August 12, 2005, have been fully considered by the examiner. In particular, applicant has canceled claims 1-7 in favor of newly filed claims 8-36. Also, applicant's terminal disclaimer filed with the August 12, 2005 response is acceptable. The following is a complete response to the August 12, 2005 communication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of the claims can not be determined. Each of these claims are method claims, but none of the claims recite even a single step. Rather, each of the claims merely recites a method of treating tissue using a device as set forth in a previous claim. Applicant must provide at least one active method step in each method claim in order to define the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8-10, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallock et al (6,235,022).

Hallock et al provide a system used in conjunction with an electrode structure (i.e. catheter) which is deployed in a tissue region (i.e. the heart). The system comprises a housing (11 – Figure 1) having a generator and a pumping mechanism incorporated in the housing (col. 1, lines 64-65). The pumping mechanism is attached to tubing (i.e. the catheter) to dispense a cooling fluid to the tissue region (col. 2, lines 9-10). A controller is also integrated in the housing (col. 2, lines 11-15), the controller including a computer (col. 3, lines 44+). A user interface (21) is coupled to the controller, and a keyboard is used to input command inputs including heating and cooling profiles. The user interface displays a first visual image relating to the generator control input (e.g. temperature or impedance – see col. 5, lines 52-55) and a second visual image in association with the pump control input (see col. 5, lines 15-30). As disclosed at column 5, lines 52-64, delivery of energy is controlled based on monitored impedance and/or temperature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallock et al (6,235,022) in view of the teaching of Cosman (6,241,725).

The Hallock et al device has been addressed previously. While Hallock et al disclose the use of a display screen to show various operating conditions, including fluid pumping, temperature and impedance, there is no explicit teaching of providing an idealized image of the electrode structure.

Cosman, as addressed in previous Office actions, discloses another RF treatment system that includes the use of a display means to provide an idealized image of an RF electrode structure as well as the operating parameters associated with the electrode structure. The display means provides graphic feedback of the electrode position in the body as well as the display of parameters of the system during operation.

With regard to the specific display items (i.e. a faucet or an icon), the examiner maintains that one of ordinary skill in the art would recognize that any desired image may capable of providing relevant feedback may be shown on the display. Applicant has not shown an unexpected result or any criticality associated with the various elements that may provided on the display.

To have provided the Hallock et al system with a graphic display to show an idealized image of the electrode within the body along with the various operating parameters would have been an obvious consideration for one of ordinary skill in the art, particularly since Cosman teaches that it is known to provide such a graphic representation of an electrode system deployed in the body.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallock et al (6,235,022) in view of the teachings of Cosman (6,241,725) and Edwards et al (5,370,675).

Hallock et al disclose a device including a display for showing various parameters associated with a deployed electrode device, and Cosman provides the teaching of displaying a graphic representation of the electrode device in the body. Hallock et al fails to specifically disclose a catheter having tissue-piercing electrodes.

Edwards et al discloses another RF catheter device for treating the prostate. The Edwards et al device also includes means to provide a fluid through the electrodes. The examiner maintains that the device is inherently capable of being used to treat tissue at or near a sphincter, and that applicant's recitation in claim 21 is directed solely to the intended use of the device. It is the examiner's position that any well-known electrode catheter device may have been used with the Hallock et al system.

To have provided any alternative RF electrode device in the Hallock et al system, as modified by the teaching of Cosman, to allow for the visualization of operating parameters associated with the electrode device would have been an obvious consideration for one of ordinary skill in the art.

Claims 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallock et al (6,235,022) in view of the teachings of Cosman (6,241,725) and Baker (6,197,022).

The combination of the Cosman teaching with the Hallock et al device has been addressed previously. Neither Cosman nor Hallock et al disclose the specific treatment of sphincter tissues or the treatment of upper gastrointestinal tract tissues.

Baker discloses another RF catheter device and specifically teaches the use of such a device to treat upper and lower GI tract disorders, as well as incontinence (see title, abstract). Again, the examiner maintains that it would have been obvious to one of ordinary skill in the art to have provided any alternative RF electrode device in the Hallock et al system to provide for monitoring and control of the device during a procedure.

With regard to the various claimed procedures, the examiner maintains that use of the Baker device for any similar procedure, such as the treatment of fecal incontinence, would be an obvious consideration for one of ordinary skill in the art. Applicant's specification provides no distinction between the performances of the various procedures. Rather, applicant's specification seems to indicate that the various treatments are all obvious alternatives with no particular patentable distinction afforded to any individual procedure.

Response to Arguments

Applicant's arguments with respect to claims 8-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

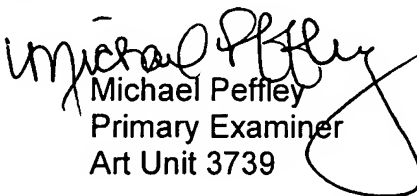
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
October 17, 2005